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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,890	09/15/2006	Massimo Prini	P48612	2374

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EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
08/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/567,890	PRINI, MASSIMO
	Examiner	Art Unit
	JAKE VU	1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/6/11*.	6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Information Disclosure Statement filed on 06/06/2011.

- Claim 1 has been amended.
- Claims 1-4 are pending the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, pertaining to the phrase "the only material used for converting the composition into a gel and to render it bioadhesive" **is maintained** for reasons of record in the office action filed on 03/11/2011.

Applicant argues that when one reads the entire phrase, and not just the truncated portion quoted by the Examiner, the meaning of the text is immediately apparent. That is, the applicant is not generically claiming "any" material that would convert the composition into a gel and render it bioadhesive. Rather, applicant is claiming a specific material having this function. That is, the claim recites that hydroxyethylcellulose is the only material used for converting the composition into a gel and to render it bioadhesive. Anyone of ordinary skill in

this field would well understand what a 'gel' is. The Examiner argues, in support of the rejection, that applicant provides no list of common gelling agents or what formula would constitute a "material used for converting the composition into a gel and render it bioadhesive". As indicated above, however, applicant does not need to provide such a list as he is presently claiming a specific species and not a genus. That is, applicant is under no obligation to disclose or otherwise teach one how to define the genus of all materials that could be used for converting the composition into a gel and to render it bioadhesive. Instead, applicant is instead reciting in claim 1 a specific material (a species) that fulfills the requirement, i.e., hydroxyethylcellulose. The fact that other materials may perform this function is moot insofar as applicant's responsibility under 35 U.S.C. 112, second paragraph is concerned. Applicant is not simply describing the claimed material by its function, i.e, in that it converts the composition into a gel and renders it bioadhesive. The material performing the indicated function is, moreover, specifically identified as hydroxyethylcellulose. Simply put, an applicant is under no obligation to define a genus when what is being claimed is, in fact, a species that is specifically identified, i.e., in this case as hydroxyethylcellulose. The Office Action goes on to state, at the bottom of p. 3, that applicant provides no standard for ascertaining what a 'material used for converting the composition into a gel and to render it bioadhesive' would encompass. Based on this, the Examiner states that one of ordinary skill in the art would not be reasonably apprised of the scope of the term, 'material used for converting the composition into a gel and to render it bioadhesive'. In response, applicant submits that a skilled artisan need

only look to lines 4-5 wherein the claim recites, clearly and unambiguously, that hydroxyethy1cellulose is the (only) material used for converting the composition into a gel and for rendering it bioadhesive. Since the meanings of 'gel' and 'bioadhesive' are, as indicated above, not in dispute and since 'hydroxyethylcellulose' is a known compound, applicant submits that there is no ambiguity at all present in the claim language.

The Examiner finds this argument unpersuasive, because the Examiner is not arguing that the specie “hydroxyethylcellulose" is indefinite. Rather, the Examiner is arguing that the phrase of excluding "materials used for converting the composition into a gel and to render it bioadhesive” is indefinite. This is a positive limitation on the claim and must not be indefinite. As discussed in the previous office action, Applicant provides no list of materials or what formula would constitute a "material used for converting the composition into a gel and to render it bioadhesive". Additionally, Applicant states that “example [such as hydroxyethylcellulose, acrylic or methacrylic acid polymers, chitosan, and polycarbophil] at p. 1 of the specification, are provided as non-limiting examples of gelling agents” (see Applicant reply filed on 09/14/2009 on pg. 5-6) provide no standard for ascertaining what the "material used for converting the composition into a gel and to render it bioadhesive" would encompass, and one of ordinary skill in the art would not be reasonably apprised of the scope of the term "material used for converting the composition into a gel and to render it bioadhesive". For example, Applicant’s claim recites “glycerol”, wherein the Sigma-Aldrich catalog

(http://www.sigmaaldrich.com/catalog/ProductDetail.do?D7=0&N5=SEARCH_CONCAT_PNO%7CBRAND_KEY&N4=G8773%7CSIGMA&N25=0&QS=ON&F=SPEC) teaches that "glycerol is used both in sample preparation and gel formation for polyacrylamide gel electrophoresis", which would read on " a "material used for converting the composition into a gel and to render it bioadhesive", since any gel or any material, such as paper, would have at least some bioadhesiveness (even though the bioadhesiveness is not strong, there is still bioadhesiveness). Thus, Applicant is excluding another "material used for converting the composition into a gel and to render it bioadhesive" while claiming an additional "material used for converting the composition into a gel and to render it bioadhesive". This is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 3 and 4 rejected under 35 U.S.C. 102(b) as being anticipated by ARKIN et al (US 2003/0039704) **are maintained** for reasons of record in the previous office action filed on 04/14/2009, 12/16/2009, 03/11/2011 and as discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 rejected under 35 U.S.C. 103(a) as being unpatentable over ARKIN et al (US 2003/0039704) **are maintained** for reasons of record in the previous office action filed on 04/14/2009, 12/16/2009, 03/11/2011 and as discussed below.

Response to Arguments

Applicant argues that the features that the composition (1) delivers at least one of active ingredients and principles to a subject's vaginal mucosa; and that the composition is adapted so as to render it (2) bioadhesive to the vaginal mucosa are no longer recited 'merely' in the preamble of the subject claim wherein it can be treated as not constituting a claim limitation. Instead, the indicated language is now found in the body of the claim wherein it must be considered as regards its impact on the patentability of the composition so claimed. Thus, as previously argued in applicant's response dated March 16, 2010, the claimed composition is a composition that is specifically adapted for the delivery of at least one of active ingredients and principles to the vaginal mucosa of a subject in need thereof, wherein the composition is, in fact,

bioadhesive to the vaginal mucosa, whereas Arkin et al., in contrast, is directed to pharmaceutical preparations adopted for topical administration for treating rosacea. As was previously noted in applicant's prior response, one having an ordinary level of skill in the relevant art would know, rosacea is a specific pathology affecting the skin, not the mucosa and particularly not the vaginal mucosa. The Arkin et al reference does not disclose a mucoadhesive formulation as recited in, e.g, claim 1, that is adapted for delivery to a subject's vaginal mucosa, or wherein the composition is bioadhesive to the vaginal mucosa.

The Examiner finds this argument unpersuasive, because the intended use of “adapted for the delivery of at least one active ingredients and principles to the vaginal mucosa of a subject in need thereof, wherein the composition is, in fact, bioadhesive to the vaginal mucosa” in the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this instance, the prior art teaches a composition that has all the ingredients as claimed by Applicant and is a gel, which would inherently be capable of being placed in the vaginal mucosa for delivery of at least one active agent; and would inherently be bioadhesive to the vaginal mucosa, since the prior art's composition has hydroxyethylcellulose.

Applicant argues that the composition disclosed by Arkin et al is for treating rosacea and, as such, it is topically applied upon the surface of the user's

skin. It does not deliver an active ingredient and/or principle to the vaginal mucosa of a subject in need thereof, nor is it bioadhesive to the subject's vaginal mucosa. Furthermore, there is no suggestion anywhere within the Arkin et al reference that would suggest modifying the composition disclosed therein to one having an ordinary level of skill in this art such that it would meet the above-noted requirements recited in claim 1. That is, the treatment of rosacea does not call for delivering active ingredients and/or principles to the vaginal mucosa of a subject, i.e., due to the fact that rosacea is well-known to be a specific pathology affecting the skin. Furthermore, due to the fact that the Arkin et al composition is topically applied to the skin, the reference contains no teaching or suggestion to modify the composition(s) disclosed therein to render them, as recited in applicant's claim 1, bioadhesive to the vaginal mucosa.

The Examiner finds this argument unpersuasive, because Applicant's claims are not directed to a method of delivering drug to a vaginal mucosa, where a requirement of topical application to the vaginal mucosa would be a positive limitation. Rather, Applicant’s claims are directed to a composition. The prior art teaches the same composition as claimed by Applicant and in the form of a gel as claimed by Applicant, which would inherently be capable of delivering drug to the vaginal mucosa; thus would read on Applicant's limitation of "adapted for the delivery of at least one of active ingredients and principles to vaginal mucosa".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618